

REMARKS

The Examiner rejected claims 25-28 under 35 U.S.C. § 112, second paragraph for insufficient antecedent basis; claims 1, 4-10, 14, 17-19, and 25-28 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,733,297 to Forber et al.; claims 11, 13, and 20 under 35 U.S.C. § 103(a) over Forber in view of U.S. Patent No. 6,117,519 to Huebsch et al.; and claims 12, 21, and 22 under 35 U.S.C. § 103(a) over Forber in view of Huebsch, and further in view of U.S. Patent No. 6,355,052 to Neuss et al.

Applicants amend claims 25-28 and submit that claims 25-28 are now in compliance with 35 U.S.C. § 112, second paragraph. Applicants also amend claim 1 and cancel claim 5. After entry of this paper, claims 1, 4, 6-14, 17-22, 25-28 will be pending in this application. Applicants submit that these amendments add no new matter.

Claim Amendments

Applicants amend claim 1 to incorporate the subject matter of claim 5. Accordingly, claim 1 as amended recites that, *inter alia*, an apparatus comprises a patent foramen ovale (PFO) closure device having a deployed configuration for providing compressive force to septum primum and septum secundum. The device has a central body, two end cap, and two wire-defined loops extending from the central body to one end cap at each side of the septum. The two loops on the same side of the PFO define a plane substantially parallel to the overlapping septum primum and septum secundum, and cooperating with the central body to apply a force to the overlapping layer of the septum. The two end caps are skewed relative to a line perpendicular to the septum primum and septum secundum. Support for the amendment can be found in paragraph [0025] of the published application. Accordingly, Applicants cancel claim 5. Applicants submit that the amendment to the claim introduce no new matter.

Applicants also amend claims 25-28 to correct the antecedent basis. Support for these amendments can be found in the application as originally filed, for example, in FIGs. 5A and 5B. Applicants submit that the amendments to these claims introduce no new matter.

Claim Rejections – 35 U.S.C. § 112

The Examiner rejected claims 25-28 under 35 U.S.C. § 112, second paragraph for insufficient antecedent basis. Applicants respectfully submit that claims 25-28 as amended each has the proper antecedent basis and therefore are now in compliance with 35 U.S.C. §

112, second paragraph. Accordingly, Applicants request that the Examiner re-consider and withdraw the above rejections.

Claim Rejections – 35 U.S.C. § 102(b)

The Examiner rejected claims 1, 4-10, 14, 17-19, and 25-28 under 35 U.S.C. § 102(b) and alleged that they were anticipated by Forber. Applicants respectfully submit that Forber failed to teach or suggest all of the limitations in the claims as amended. Specifically, Forber failed to teach that a PFO closure device, in its deployed configuration, has a central body extending through the PFO, two loops on each side of the septum defining a plane substantially parallel to the septum primum and septum secundum, and two end caps of the device skewed relative to a line perpendicular to the septum primum and septum secundum.

Specifically, claim 1 recites, *inter alia*, that a device, in its deployed configuration comprises a central body extending through the PFO, two wire-defined loops on one side of the PFO defining one plane substantially parallel to septum primum and septum secundum, another two wire-defined loops on the other side of the PFO defining another plane also substantially parallel to septum primum and septum secundum, and two end caps being skewed relative to a line perpendicular to the septum primum and septum secundum.

Forber failed to teach these required limitations. Forber taught a self-expanding cardiovascular occlusion apparatus with two disk-like patterns of loops on each side of the septum, along with three collinear band assemblies positioning in the middle, and at the two ends of the apparatus. Forber, col. 4 lines 15-18, and col. 3, lines 20-22; and Figs. 3, 6, and 8. Forber discloses that the device is used to treat holes in the septal wall of a heart. Forber, col. 5, lines 66-67; and Fig. 8. Therefore, as Forber device deployed at the treatment site, the two disk-like patterns of loops are positioned on each side of the septal defect, and the middle collinear band assembly is positioned inside the hole on the septal wall. Applicants submit that the planes defined by Forber's loops are parallel to the septum. At the same time, these loops are perpendicular to the middle collinear band assembly. This is because that the septal defect, i.e., the hole, is on the septal wall. Therefore the longitudinal axis of the hole is generally perpendicular to the septum. Finally, when the middle collinear band assembly of the Forber device is positioned within the hole, it lies along the longitudinal axis of the hole and is therefore also generally perpendicular to the septum. Furthermore, as shown in Figs. 6 and 8, the two collinear band assemblies at the end of the Forber device are in a line with the middle collinear

band assembly, such that they are in line with a line perpendicular to the septum, **not** skewed relative to the line perpendicular to the septum, as in the Applicants' claimed inventions.

A PFO generally is a flap-like opening in the wall between the right atrium and the left atrium of the heart. Thus, a PFO is a passageway between the overlapping septum primum and septum secundum. As a result, the longitudinal axis of the PFO, as shown in the Fig. 1 of the present Application, is **not** perpendicular to the septum. When an Applicants' claimed device is deployed to close a PFO, the central body extends through the PFO. Thus, the central body of the device is **not** perpendicular to the septum. Furthermore, in an Applicants' claimed invention, when deployed, the loops of the Applicants' device form planes substantially parallel to the septum. Thus, the planes defined by these loops are **not** perpendicular to the PFO, i.e., the passageway between the septum primum and septum secundum. Neither are these loop-defined planes perpendicular to the central body of the Applicants' device. Lastly, the two end caps in each of the Applicants' claimed inventions, which are across from corresponding ends of the central body, are skewed relative to, but **not** in line with, a line perpendicular to the septum.

Thus, the Applicants' claimed inventions are not anticipated by Forber. Specifically, as shown in Figs. 6 and 8 of Forber, the disk-like patterns of the loops are perpendicular to the middle portion of the Forber device. In contrast, the loops of Applicants' devices are not perpendicular to the central body. Moreover, unlike the deployed configuration and intended purpose of the Forber device, because the passageway of PFO is not perpendicular to the septum, the two end caps of the Applicants device are skewed relative to a line perpendicular to the septum.

Based on the above discussions, Applicants respectfully submit that Forber failed to teach at least some of the required limitations in claim 1 and claim 1 is therefore novel. Further, because claims 4, 6-10, 14, 17-19, and 25-28 depend on claim 1, they are also novel over Forber. Accordingly, Applicants request that the Examiner re-consider and withdraw these rejections.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner rejected claims 11, 13, and 20 under 35 U.S.C. § 103(a) over Forber in view of Huebsch. In addition, the Examiner also rejected claims 12, 21, and 22 on the same ground over Forber in view of Huebsch in view of Neuss. Applicants submit that neither Forber in view of Huebsch nor Forber in view of Huebsch in view of Neuss makes the claimed inventions obvious.

As discussed above, Forber failed to teach or suggest at least some of the required limitations in claim 1. Specifically, Forber failed to teach or suggest that a PFO closure device, in its deployed configuration, has a central body extending through the PFO, two loops on each side of the septum defining a plane substantially parallel to the septum primum and septum secundum, and two end caps of the device skewed relative to a line perpendicular to the septum primum and septum secundum. Huebsch and Neuss, either individually or in combination, did not cure these defects.

Specifically, the Examiner states that Huebsch teaches a bioresorbable device covered in a material to promote tissue ingrowth. Office Action at page 6. The Examiner also states that Huebsch teaches delivering the PFO closure device through a catheter, and drawing the device back into the catheter, and that Neuss teaches a PFO closure device having loops made of a bioresorbable material. *Id.* at p. 7. However, none of the above teachings addresses Forber's failure in teaching a PFO closure device with a central body extending through the PFO, two loops on each side of the septum defining a plane substantially parallel to the septum primum and septum secundum, and two end caps of the device skewed relative to a line perpendicular to the septum primum and septum secundum..

As a result, to persons with ordinary skills in the art, claims 11, 13, and 20 would not have been obvious over Forber and Huebsch, individually or in combination; and claims 12, 21, and 22 would not have been obvious over Forber, Huebsch, and Neuss, individually or in combination.. Accordingly, Applicants request that the Examiner reconsider and withdraw the above rejections.

CONCLUSION

Applicants submit that the claims are now in condition for allowance. Accordingly, a favorable action is thereby respectfully requested. The Examiner is invited to telephone the undersigned to discuss any outstanding issues.

Respectfully submitted,

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